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## The Treatment of Uncertainty in EPA's Analysis of Air Pollution Rules: A Status Report

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# The Treatment of Uncertainty in EPA's Analysis of Air Pollution Rules: A Status Report

Arthur G. Fraas

## Abstract

An understanding of the uncertainty in benefit and cost estimates is a critical part of a benefit–cost analysis. Without a quantitative treatment of uncertainty, it is difficult to know how much confidence to place in the benefit–cost estimates associated with regulatory analysis. In 2002, an NRC report recommended that EPA move toward conducting probabilistic, multiple-source uncertainty analyses in its RIAs with the specification of probability distributions for major sources of uncertainty in the benefit estimates. In 2006, reports by GAO and RFF found that EPA had begun to address the NRC recommendations, but that much remained to be done to meet the NRC concerns. This paper provides a further review of EPA's progress in developing a quantitative assessment of the uncertainties in its health benefits analyses for the RIAs for four recent rulemakings setting National Ambient Air Quality Standards (NAAQS). In conclusion, EPA's basic approach to presenting the uncertainty in its health benefits estimates remains largely unchanged. Recent RIAs present the results of uncertainty analysis in piecemeal fashion rather than providing an overall, comprehensive statement of the uncertainty in the estimates. In addition, the uncertainty analysis in recent RIAs continues to focus on the concentration–response relationship and largely fails to address the uncertainty associated with the other key elements of the benefits analysis.

**KEYWORDS:** EPA, benefit-cost analysis, uncertainty analysis, air pollution rules

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## Introduction

The U.S. Environmental Protection Agency (EPA) is currently undertaking a number of major regulatory initiatives. These include reviewing and revising most of the National Ambient Air Quality Standards (NAAQS),<sup>1</sup> crafting associated implementation regulations that will result from those revisions, updating New Source Performance Standards and air toxics standards for many categories of stationary sources, and setting mobile source standards to address emissions of conventional pollutants (such as nitrogen oxide, NO<sub>x</sub>) and greenhouse gases.

EPA, like other federal agencies, conducts analyses to provide information about the consequences—specifically the benefits and costs—of such regulatory actions. The agency has estimated that just a subset of these actions could yield reductions of tens of thousands of premature deaths per year with projected annual health benefits of tens of billions of dollars per year (EPA 2006, 5-69 and 5-78; EPA 2009b, 5-36; EPA 2010, S3-5 and S3-6). Unfortunately, EPA's current analyses provide only a limited quantitative uncertainty analysis for its regulatory impact analyses (RIA), one that likely understates uncertainty significantly.

In a 2002 report, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, the National Research Council (NRC) of the National Academy of Sciences raised specific and detailed concerns with EPA's treatment of uncertainty in its health benefits analysis.<sup>2, 3</sup> While previous recommendations varied over the best way to address uncertainty, the 2002 report was unequivocal in recommending that EPA conduct a more comprehensive quantitative assessment of uncertainty in its primary regulatory analysis. The NRC report specifically stated that this change would require EPA to conduct probabilistic, multiple-source uncertainty analyses and make available a presentation that would

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<sup>1</sup> The NAAQS establish ambient standards for key air pollutants and are the flagship rules of the Clean Air Act (CAA). While the CAA prohibits consideration of cost in setting the NAAQS, the agency prepares an RIA in order to satisfy the requirements of Executive Order 12866 and inform the public about the potential benefits and costs of alternative standards.

<sup>2</sup> Earlier NRC reports raised similar concerns. These earlier reports found that proper characterization of uncertainty is essential and most have expressed the concern that analyses of health benefits understate associated uncertainties and leave decisionmakers with a false sense of confidence in the health benefits estimates.

<sup>3</sup> While the 2002 NRC report focused on uncertainty in the analysis of health benefits of air pollution regulations, it also recommended that EPA perform a similar quantitative uncertainty analysis for the valuation of health benefits and for the regulatory cost analysis. (NRC 2002, 127 and 148).

be clear and transparent to decisionmakers and to other interested readers (NRC 2002, 7-8).

Determining the benefits of EPA air rules typically requires a complex chain of analyses, including establishment of baselines such as the demographics and health status of the exposed population, estimates of the change in emissions with regulatory action, the effect of emissions changes on air quality, the resulting changes in the exposure of the population, and the resulting effect of changes in exposure on health. Because of the potential compounding of high-end or low-end assumptions in developing benefits estimates, it is not possible, to determine whether the estimates provided by an RIA are within the ballpark of likely effects without a quantitative uncertainty analysis. They may be too high, if all the assumptions and defaults are conservative, or too low, if the opposite is true.

By developing probability distributions for each of the key components and combining these for the primary estimate, a quantitative uncertainty analysis would place EPA's estimates of benefits in the context of a comprehensive probability distribution. This would provide a better characterization of the EPA estimates and their uncertainty.<sup>4</sup>

A July 2006 U.S. Government Accountability Office (GAO) report found that EPA had started to address a number of the NRC recommendations in its draft RIA for the 2006 NAAQS for particulate matter (PM), but that a "continued commitment and dedication of resources will be needed if EPA is to fully implement the improvements endorsed by the National Academies" (GAO 2006, 15). Other recent reports have also urged EPA to make greater progress in the quantitative treatment of uncertainty.<sup>5</sup>

This paper finds that EPA's basic approach to presenting the uncertainty in its health benefits analysis remains largely unchanged eight years after the 2002 NRC report. My analysis follows the lead of the 2002 NRC report and the 2006 GAO report by addressing the uncertainty in EPA's RIA analyses of the quantified health benefit estimates in four recent proposed and final NAAQS

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<sup>4</sup> Throughout this discussion, "quantitative uncertainty analysis" refers to both "variability" that reflects the statistical variation in estimates as well as to the uncertainty associated with a more fundamental lack of knowledge. Variability comes from the fact that there is variation within a population in terms of differences in exposure and in susceptibility. Variability cannot be reduced, but it can be better characterized with better data. Uncertainty results from a lack of knowledge about key elements or processes in the risk assessment. It can be represented by quantitative analysis—and can be reduced with additional research. (For a more complete discussion, see NRC 2009a, 93-99.)

<sup>5</sup> For example, see Krupnick et al. 2006. See also NRC 2007a, 114-117 ; NRC 2007b, 6-8; Keohane 2009, 45-47; NRC 2009a, 6.

rulemakings—ozone, lead, nitrogen dioxide (NO<sub>2</sub>), and sulfur dioxide (SO<sub>2</sub>)—that were completed after the 2006 GAO report.<sup>6</sup> Each of these four RIAs included options with estimated benefits that exceed \$1 billion per year. These analyses are state of the art compared to earlier regulatory analysis by EPA and reflect key changes in the benefits methodology. This paper also covers several recent papers and reports that have implications for and ought to be incorporated into EPA's quantitative uncertainty analysis for health benefits.

## Background

### *Why Quantitative Uncertainty Analysis is Important*

The literature on the treatment of uncertainty in policy analysis offers a number of compelling reasons for quantitative uncertainty analysis (Morgan and Henrion 1990; Krupnick et al. 2006); NRC (2009); some of the key reasons cited by this literature include:

The development of a benefit/cost analysis may yield "...'best estimates' that are not actually very good." (Morgan and Henrion 1990, 44.) Without a quantitative uncertainty analysis, it is not possible to know whether the range of estimates provided by an RIA overstate or understate the relevant distribution of outcomes. The quality of the analysis would be significantly improved by a quantitative uncertainty analysis.

The benefit/cost analysis should help to identify the most important factors affecting the problem or issue subject to analysis, and the uncertainties that attend these factors. A quantitative uncertainty analysis helps both the analyst and the reader in thinking through these effects in a more thorough way. (Morgan and Henrion 1990, 3 and 44.)

Presenting a quantitative uncertainty analysis with the RIA informs the decisionmaker and the public about the range of

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<sup>6</sup> Because this analysis focuses on the issues raised by the 2002 NRC report, this analysis does not address EPA's treatment of uncertainty in the valuation of health benefits or the costs of the rule. However, the reasons presented in the 2002 NRC report—and in this paper—for a quantitative uncertainty analysis with regard to health effects also apply with equal force to the importance of performing such an analysis for the valuation of health benefits and for the cost of the rule. Addressing uncertainty for health effects without addressing uncertainty in these other areas is akin to having only one hand clapping.

potential risks associated with the decision. The uncertainty analysis helps in evaluating alternatives in terms of identifying both the most likely and worst outcomes. In the absence of such analysis, decisionmakers may choose an option that fails to meet key policy objectives such as achieving an assured level of risk reduction or of net benefits. (Krupnick et al. 2006)

Finally, per Morgan and Henrion (p. 44), “policy analysts have a professional and ethical responsibility to present...a clear and explicit statement of the implications and limitations of their work.”

### ***EPA’s Approach to Uncertainty Analysis at the Time of the NRC Review***

EPA used a two-part approach to provide a quantitative assessment of the uncertainty in the health benefits analyses for the four RIAs reviewed by the 2002 NRC report. First, EPA prepared a primary analysis that provided a probability distribution for each health outcome evaluated. These probability distributions incorporated only one source of uncertainty—the random sampling error associated with the effect estimates from the selected health studies. Second, EPA presented ancillary sensitivity analyses only in an appendix to each RIA, instead of incorporating such analysis in the main body of its benefits analysis. While these analyses included alternative calculations for some uncertainties and sensitivity analyses for others, they typically examined only one source of uncertainty at a time.

### ***NRC Committee: Estimating the Public Health Benefits of Proposed Air Pollution Regulations***

The 2002 NRC report was critical of EPA’s approach in evaluating the uncertainty in its health benefits analysis. With respect to the primary analysis, the report stated that “...no estimate can be considered best if only one of the large number of uncertainties is included in the analysis producing that estimate.”<sup>7</sup> (NRC 2002, 138) In addition, the NRC report found “...that the mean of the distributions should not be interpreted as ‘best’ estimates, and the intervals between the 5<sup>th</sup> and 95<sup>th</sup> percentiles of the distributions should not be interpreted

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<sup>7</sup> The NRC report also noted that “Because of the lack of consideration of other sources of uncertainty, the results of the primary analysis often appear more certain than they actually are.” (NRC 2002, 11).

as '90 percent credible intervals,' within which 'the true benefit lies with 90 percent probability' (U.S. EPA 1999a, p. 3-26.)" (NRC 2002, 134).

With respect to EPA's ancillary sensitivity analysis in the appendices to these RIAs, the NRC report observed that by limiting the analyses to focus on one source of uncertainty at a time these analyses "...do not adequately convey the aggregate uncertainty from other sources, nor do they discern the relative degrees of uncertainty in the various components of the health benefits analysis" (NRC 2002, 10-11). The report recommended that:

EPA should move the assessment of uncertainty from its ancillary analyses into its primary analyses to provide a more realistic depiction of the overall degree of uncertainty. This shift will entail the development of probabilistic, multiple-source uncertainty models based not only on available data but also on expert judgment. EPA should also continue to use sensitivity analyses but should attempt to include more than one source of uncertainty at a time (NRC 2002, 11).

In short, EPA presents its estimates in a way that makes them appear far more certain than they actually are. Nonetheless, there may be a compelling need for government decisions on regulatory action to protect public health and the environment even where there is great uncertainty. As the NRC report noted, "Decisions about whether to act, when to act, and how aggressively to act can only be made with some understanding of the likelihood and consequences of alternative courses of action" (NRC 2002, 126).

The NRC report also identified specific areas of uncertainty in the analysis of health benefits—Boundaries and Baselines, Exposure Assessment, Health Assessment, and Concentration-Response Functions that deserve to be evaluated quantitatively (NRC 2002, 5-9). My review focuses on the following as critical components of a quantitative uncertainty analysis.

### **Boundaries and Baselines**

1. Population Demographics and Heterogeneity: For example, predictions about future populations, such as predicted population growth and changes in age distribution (NRC 2002, 6).
2. Health Baseline: Projections of baseline health status (NRC 2002, 6).

### **Exposure Assessment**

3. Estimated Changes in Emissions: For example, there is uncertainty about the extent of compliance and the effectiveness of projected control requirements (NRC 2002, 5-6).
4. Air Quality Modeling: That is, the effect of emissions on ambient air quality (NRC 2002, 6).
5. Ambient Air Concentrations Adequately Represent Actual Exposure: That is, whether predicted ambient concentrations of a pollutant adequately represent human population exposures (NRC 2002, 7).

### **Health Outcomes**

6. Causality between Pollutant Exposures and Adverse Health Outcomes (NRC 2002, 8).
7. Toxicity of PM Components: That is, evaluation of a range of alternative assumptions regarding relative particle toxicity in its uncertainty analyses instead of assuming that all particle types are equivalent in potency (NRC 2002, 7).

### **Concentration-Response Functions**

8. Validity and Precision of the Concentration-Response Functions: For example, the imprecision of exposure and response measures, functional form (and threshold), lag structures, potential confounding factors, and extrapolation from the study population to the target population in the benefits analysis (NRC 2002, 9).

As discussed in greater detail below (and summarized in Tables 1 and 2), EPA's effort in response to the 2002 NRC report has focused on the concentration-response relationship (as in point 7 above) between exposure to fine PM and the risk of premature mortality. EPA has made little progress in recent RIAs toward addressing the other sources of uncertainty identified by the 2002 NRC report.

### ***OMB Circular A-4***

In 2003, the Office of Management and Budget (OMB) issued Circular A-4 to provide guidance to the federal agencies on the development of regulatory



analysis required by Executive Order 12866 and the Regulatory-Right-to-Know-Act.<sup>8</sup> Circular A-4 includes an expanded discussion on the treatment of uncertainty in a regulatory analysis and specifically requires a formal quantitative uncertainty analysis for rules with benefits or costs that exceed one billion dollars per year.<sup>9</sup>

Circular A-4 notes that the analysis does not need to be exhaustive; that there will need to be a balance between thoroughness and the practical limits of conducting an analysis. It places the emphasis on "...first resolving or studying the uncertainties that have the largest potential effect on decision-making" (OMB 2003). The discussion below recognizes the need to consider practical considerations in shaping the scope and extent of the uncertainty analysis.

### ***GAO's Report to Congress***

GAO issued its July 2006 report "EPA Has Started to Address the National Academies' Recommendations on Estimating Health Benefits, but More Progress Is Needed" on the extent to which EPA had responded to the NRC recommendations in its January 2006 draft RIA for the proposed rule revising the particulate matter NAAQS. GAO found that EPA fully "applied" eight of the recommendations and that EPA partially responded to another 16 recommendations—approximately two-thirds of the Academies' recommendations—in its January 2006 regulatory impact analysis (GAO 2006, 7). However, many of the EPA responses addressed recommendations for changes

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<sup>8</sup>Circular A-4 revised OMB's earlier 1996 "best practices" document and a revised version issued as an OMB guidance in 2000.

<sup>9</sup>Circular A-4 also includes other requirements. For example, it requires that the analysis should consider both the statistical variability and the uncertainty associated with incomplete knowledge about relevant relationships. It also provides that the treatment of uncertainty must be guided by the same principles of transparency and full disclosure that apply to other elements of the regulatory analysis.

to the RIA that were not related to the development of a quantitative uncertainty analysis.<sup>10</sup>

GAO found EPA had fully applied only two of the eight uncertainty-related recommendations identified above—both associated with the assumption of causality and the concentration-response relationship between PM exposure and premature mortality—and partially addressed another in the draft 2006 RIA for the PM NAAQS.<sup>11</sup> GAO specifically noted that even with EPA’s expert elicitation study, “...the health benefits analysis does not similarly assess how the benefit estimates would vary in light of other key uncertainties as the Academies had recommended” (GAO [2006], p. 3.). With respect to other key uncertainties, GAO cited uncertainty about the effects of age and health status of people exposed to particulate matter and estimates of exposure to particulate matter, as examples of areas that should be addressed as a part of a quantitative uncertainty analysis.<sup>12</sup>

### **Status of EPA Uncertainty Analysis in Recent RIAs**

Since 2006, EPA has not made further progress (as indicated in Table 1 and Table 2) in addressing many of the concerns raised by the 2002 NRC report—in particular, the uncertainty associated with exposure analysis and air quality modeling. EPA continues to use, largely unchanged, the basic approaches reviewed by the 2002 NRC report in presenting a quantitative uncertainty analysis

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<sup>10</sup>Of GAO’s eight fully “applied” recommendations, for example, only two were directly related to developing a quantitative uncertainty analysis. Of the remaining recommendations, three suggested further EPA review of the basis for estimated health effects in the primary analysis (e.g., using C-R functions from acute studies that integrate over multiple days or weeks, rather than rely on studies with a lag of 1 or two days) and two addressed presentation (e.g., rounding to fewer significant digits) and transparency (e.g., providing clear and accurate references to the technical supporting documents) issues. Finally, GAO reported that EPA decided not to adopt one of the eight recommendations—i.e., providing an estimate of health benefits for the current population resulting from the expected change in emissions—because it would not provide meaningful information to the analysis (GAO 2006, Appendix II, 20-28).

<sup>11</sup> GAO 2006, 9. See Appendices II & III of the GAO report for NRC report recommendations “applied” and “not applied” to the 2006 draft RIA. (GAO 2006, Appendix II and III, 20-28 and 29-38).

<sup>12</sup> Other recent reports have also urged EPA to make greater progress in developing a quantitative treatment of uncertainty. For example, see Krupnick et al. 2006. See also NRC 2007a, 114-117; NRC 2007b, 6-8; Keohane 2009, 45-47; NRC 2009a, 6.

for its benefits estimates.<sup>13</sup> In particular, these RIAs continue to develop a primary analysis for presenting incidence estimates based on concentration-response functions from selected studies (or groups of studies). These estimates include “95<sup>th</sup> percentile confidence intervals” based on the standard errors of the effect estimates taken from the selected studies for each of the health endpoints.<sup>14</sup> EPA uses Monte Carlo methods to generate the confidence intervals around the health incidence estimates and the monetized benefit estimates.<sup>15</sup> The problem with doing so is that other key elements—for example, projected reductions in emissions and exposure—are treated as known without uncertainty in the Monte Carlo analysis.<sup>16</sup> As noted above, the 2002 NRC report criticized this approach stating that where only one of the large number of uncertainties is considered in the analysis “...no estimate can be considered best” and stated that the range should not be interpreted as representing a 90 percent “credible interval.”<sup>17</sup>

In EPA’s most recent RIAs for rules establishing other NAAQS (ozone, lead, nitrogen dioxide, and sulfur dioxide), EPA has adopted a benefits-per-ton methodology for estimating the co-benefits associated with ancillary PM control. The resulting estimated health benefits from reduced exposure to PM has represented an important co-benefit of the regulatory action—accounting for more than 90 percent of estimated benefits in most cases. However, the adoption of this

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<sup>13</sup> The agency does acknowledge the 2002 NRC critique of its uncertainty analysis as a part of the RIA discussion of “Limitations and Uncertainties,” stating in response that it “...is developing a comprehensive strategy for characterizing the aggregate impact of uncertainty in key modeling elements on both health incidence and benefits estimates. Components of that strategy include emissions modeling, air quality modeling, health effects incidence estimation, and valuation.” There is no evidence, however, of further progress on these fronts. EPA 2009a, 5-34. See also EPA 2008a 6-5, 6-6 and EPA 2009b, 5-55.

<sup>14</sup> For example, see EPA SO<sub>2</sub> 2009, 5-21.

<sup>15</sup> Monte Carlo analysis involves random sampling from the probability distribution functions for the various elements that comprise a “model” (in this case, relating changes in emissions to health outcomes like increased risk of mortality). This process generates thousands of possible outcomes that allow the development of a probability distribution function for the outcome of interest, such as mortality. EPA uses the standard errors of the effect estimates to provide health effects distributions for the individual health end-points. In addition, it combines this distribution with a distribution of the value of reducing the risks of these effects (using Monte Carlo analysis) to generate a distribution for monetized benefit estimates.

<sup>16</sup> Note that it is possible to construct a platform for calculating benefits that would incorporate uncertainty for each of the components in the benefits analysis. For example, the Fast Environmental Regulatory Evaluation Tool (FERET) allows the user to represent the emissions profile as a distribution in addition to developing distributions for health effects and for their valuation. See: Farrow et al. 2001. 429–442.

<sup>17</sup> NRC 2002, 134 and 138.

approach has made it impossible for EPA to provide confidence limits on the monetized PM co-benefit estimates because the agency has not developed a quantitative uncertainty analysis of the other critical components that underlie these benefit-per-ton estimates<sup>18</sup> (U.S. EPA 2009a, 5-35.).

Instead, these RIAs present an illustrative range of alternative values. For example, EPA's recent draft RIA for its reconsideration of the ozone NAAQS proposal presents an array of estimates generated using six different ozone mortality functions, 14 different PM mortality functions, and two alternative cost methods (See Figure 1). While the unwary reader may view this array as a distribution of expected net benefits, these combinations do not represent a probability distribution; instead, they are estimates from a set of carefully selected modeling scenarios (EPA 2010a, S3-19). As a result, the identified "median" estimate does not have the properties of a median derived from a probability distribution and should not be interpreted as an unbiased, best estimate of net benefits.<sup>19</sup>

In short, despite the NRC critique, EPA has not changed its basic methodology for its primary analysis for the specific pollutant subject to regulation (ozone, NO<sub>2</sub>, or SO<sub>2</sub>). Thus, it presents a primary estimate with "confidence intervals" based solely on the use of the standard error in the effect estimates. Moreover, in recent RIAs where EPA benefits are dominated by co-benefit estimates based on a per-ton methodology for PM reductions, EPA only provides an illustrative range of alternative values and a qualitative discussion of uncertainty that is a step backwards in providing a quantitative uncertainty analysis.

### ***Alternate Concentration-Response Functions for PM Mortality (Expert Elicitation Study)***

EPA's efforts to date to provide a quantitative uncertainty analysis—both before and after the 2002 NRC report—have focused on the concentration-response relationship between exposure to air pollution and the associated health outcomes. EPA's most significant response to the NRC report took the form of a 2006 expert

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<sup>18</sup> These RIAs present point estimates of the co-benefits using effect estimates from Pope et al. (2002) and Laden, et al. (2006) as its core or primary estimates. In addition, to provide perspective on these two estimates, these RIAs also present an array of estimates using the Pope and Laden co-benefit results and the corresponding estimated co-benefits using the 12 effect coefficients for each of the experts from the EPA expert elicitation study on PM mortality.

<sup>19</sup> The "median" estimates in this figure for the three alternative ozone NAAQS standards are the only median estimates presented in the RIA.

elicitation study designed to provide a better understanding of the relationship between fine PM and premature mortality (Roman et al., 2008; Industrial Economics, Inc. 2006).<sup>20</sup> The experts addressed some of the key concentration-response related issues identified by the 2002 NRC report: causality, functional form, threshold, and magnitude of effect.

As indicated in Table 1, EPA presents the results of this expert elicitation study in its RIAs for regulations that achieve significant fine PM reductions as an array of information, including a representation of the results for each of the 12 experts.<sup>21</sup> The presentation of the results from the expert elicitation study, then, provides a different perspective—independent of the primary analysis—on the uncertainty associated with the concentration-response relationship between exposure to fine PM and premature mortality.

The expert elicitation study represents an important experimental effort but it has a significant limitation: EPA presents the views of each expert separately. The agency has declined to present an aggregate estimate, citing the issues associated with aggregating the views of the experts.<sup>22</sup> Consequently, EPA's current approach does not meet the basic goal of formal decision analysis—that is, a rigorous and theoretically justified approach for combining information about uncertainty in the form of a probability distribution.

A recent elicitation study of the fine PM-mortality relationship using European experts—a part of the Harvard Kuwait public health project—has taken the next step by combining estimates using two alternative weighting approaches:

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<sup>20</sup> A panel of EPA's Science Advisory Board—the Advisory Council on Clean Air Compliance Analysis—strongly endorsed the agency's application of the study results to the assessment of PM benefits.

<sup>21</sup> In addition to the estimates from the experts, the RIA also includes estimates based on the most recent epidemiological-based estimates from the American Cancer Society study (Pope 2002) and from the six-city study (Laden 2006).

<sup>22</sup> On this question, the SAB Advisory Council responded that the best approach depended on the context and results of the expert elicitation. Where the experts have a wide range of views, it is important to provide separate estimates for each expert (or for clusters of experts sharing similar views); but where they share similar views, it would be appropriate to provide a single distribution (or point estimate with uncertainty bounds) (U.S. EPA-SAB 2008, ii). The SAB Advisory Council also advised that the RIA approach of arraying the separate estimates for each of the experts provided a “very limited summary of the rich information about uncertainty provided by the expert elicitation.” It further identified several possible approaches for combining the information from the experts to better meet the goals of formal decision analysis (pp. 12-14).

an equal weight and a performance-based approach.<sup>23</sup> The resulting median estimate for the performance-based decisionmaker falls between the updated 2002 Pope estimate and the 2006 Laden study—and is roughly 30 percent greater than the updated 2002 Pope estimate.<sup>24</sup>

This study also examined the experts' views on the toxicity of the various components of fine PM. While the experts expressed uncertainty about their responses given the limited emerging literature on this issue, they viewed fine PM emitted directly from combustion processes as likely to be more toxic than the ambient mix of PM. In addition, they all viewed sulfate, nitrate, and crustal fine particulates as less toxic than the ambient mixture—that is, the reductions in sulfate and nitrate fine PM that provide the co-benefits for the NAAQS rules. The combined median estimates for long-term mortality associated with exposure to the least toxic component were less than half of the 2002 Pope estimate and comparable to the lower end 5<sup>th</sup> percentile estimate from the updated 2002 Pope study (Tuomisto et al. 2008, 739–742).<sup>25</sup>

The ranges for the combined estimates (between the 5<sup>th</sup> and 95<sup>th</sup> percentile) are substantially greater than the ranges reported for the 2002 Pope and 2006 Laden studies. This wider range reflects the view among the experts that the published confidence intervals—confidence intervals based on the standard error for the effect estimates from the underlying studies—significantly understate the uncertainty of the fine PM-mortality relationship.

Finally, it is worth noting that the expert elicitation study applies only to the fine PM–premature mortality relationship and does not address the uncertainty in the concentration-response relationship for the other criteria pollutants subject to the NAAQS (ozone, lead, NO<sub>2</sub>, and SO<sub>2</sub>).

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<sup>23</sup> The Harvard-Kuwait public health project carried out a comprehensive evaluation the health effects of the 1991 Kuwait oil fires. One element of this project was an expert elicitation study of the health effects of exposure to PM from the oil fires. The study results are reported by Cooke, et al, 2007, 6598-6605; and Tuomisto, et al. 2007, 732-744.

<sup>24</sup> See Table 6 in Tuomisto et al. 2007: “Comparison of estimates of all cause mortality, percent increase per 1 $\mu$ /m<sup>3</sup> increase in PM<sub>2.5</sub> (question Q1 and selected epidemiological studies).

<sup>25</sup> Note that Tuomisto et al. report that the performance-based estimate is theoretically preferable to the equal-weighted estimate. And, further, they conclude that based on better actual performance “...there is a scientific basis for preferring the performance-based decision-maker.” (Tuomisto et al. 2008, 743).

### ***Sensitivity Analysis***

EPA also performs a limited set of sensitivity analyses to identify the effect of specific assumptions on the primary benefit estimates. For the draft regulatory analysis for the 2009 SO<sub>2</sub> NAAQS proposal, for example, these sensitivity analyses suggested that the benefit estimates are relatively more sensitive to alternative threshold assumptions in the PM-mortality relationship and less sensitive to alternative assumptions on the discount rate (U.S. EPA 2009, 5-57).

EPA's most recent RIAs for the lead, nitrogen dioxide, and SO<sub>2</sub> NAAQS have responded to the NRC concerns that sensitivity analyses were presented as ancillary analyses in the Appendices to the RIA by presenting the basic results from EPA's sensitivity analysis in the body of the benefits chapter. However, in other respects, EPA's approach to and treatment of sensitivity analysis is largely unchanged from the approach reviewed by the NRC committee in 2002. In particular, EPA's sensitivity analyses continue to consider only one element of uncertainty at a time.<sup>26</sup> And, the agency presents the alternative scenarios without providing any judgment on the relative plausibility of the alternatives. As a result, the reader must integrate the information from the sensitivity analyses—as well as the other quantitative analyses developed in the RIA—in assessing the uncertainty in the health benefits estimates.

### ***Qualitative Discussion of Other Areas of Uncertainty***

EPA continues to provide a qualitative discussion of other factors that contribute to uncertainty in its health benefits analysis.<sup>27</sup> In the final RIA for the PM NAAQS, for example, EPA included both an extensive qualitative discussion of uncertainties in the benefits analysis and a table providing a list of key areas of uncertainty.<sup>28</sup> Other recent RIAs provide a similar qualitative discussion. While

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<sup>26</sup> Because OMB's Circular A-4 requires all agencies to present benefit and cost estimates using discount rates of 3 percent and 7 percent, the RIA sensitivity analyses will sometimes present estimates that also include both discount rates. In these analyses, the benefits estimates are not very sensitive to the discount rate. For example, the draft SO<sub>2</sub> RIA presents benefit estimates using both the Pope and Laden effect estimates with the two alternative discount rates. Sensitivity analyses for other key elements are presented for a single discount rate (EPA 2009, 5-57).

<sup>27</sup> The NRC committee recommended that "...EPA should emphasize even more than it has in the past the sources of uncertainty that remain unaccounted for in the primary analysis. These uncertainties should continue to be described as completely and realistically as possible" (NRC 2002, 147).

<sup>28</sup> Available at [http://www.epa.gov/ttnecas1/regdata/RIAs/proposaltrria\\_final.pdf](http://www.epa.gov/ttnecas1/regdata/RIAs/proposaltrria_final.pdf)

this qualitative discussion recognizes the importance of other sources of uncertainty in the health benefits estimates, there is little evidence of further progress in providing a quantitative uncertainty analysis for key areas of uncertainty, such as projected changes in emissions and air quality modeling.

The projected changes in emissions used in these RIAs represent one critical area deserving quantitative analysis.<sup>29</sup> In its RIAs, EPA provides only point estimates for the emissions reductions used in the analysis.<sup>30</sup> For example, the draft RIA for the SO<sub>2</sub> NAAQS proposal treats emissions reduction estimates as point estimates for individual nonattainment counties. Thus, there is no quantitative evaluation of the uncertainty in these estimates. Changes in control strategies could introduce substantial uncertainty in the benefits estimates, however, because of the heterogeneity in the benefits of control across sources and locations. For example, the recent RIA for the NO<sub>x</sub> NAAQS does not present a quantitative uncertainty analysis for the projected emissions reductions. As an illustration of the potential sensitivity of the estimates to alternative control strategies, a recent article suggests a substantial variation in PM co-benefits across sources, including negative PM co-benefits for mobile source NO<sub>x</sub> control in all of the three eastern regions considered in the analysis (Atlanta, Chicago, and New York/Philadelphia)<sup>31</sup> (Fann et al. 2009; see Table 3). As a result, a different NO<sub>x</sub> control strategy from that identified in the RIA (e.g., one triggered by violations

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<sup>29</sup> The NRC reported, for example, that "...current emissions models fail to provide an assessment of uncertainty associated with the emissions predictions for the baseline and control scenarios." (NRC 2002, 5-6). These RIAs do provide a qualitative discussion of some of the uncertainties and limitations associated with the estimated reductions. The RIAs note that they are based on an "illustrative control strategy" because actual control strategies will be determined through the State Implementation Plan process and could differ substantially—with a different mix of emissions reductions and sources—from the approach evaluated by the RIA. In addition, there are uncertainties associated with the extent of current compliance with the NAAQS.

<sup>30</sup> For example, the final RIA for the SO<sub>2</sub> NAAQS uses point estimates for required emissions reductions in individual nonattainment counties—e.g., required emission reductions to meet a 50 ppb standard of 21,000 tons in Jasper County (Indiana) and 590 tons in Bannock County (Idaho) (EPA 2010c, Table 4.4, 4-9).

<sup>31</sup> Fann et al. caution that the estimates only reflect the effect of reductions in exposure to fine PM; they do not include the benefits of any associated reductions in the exposure to other pollutants, such as ozone, NO<sub>x</sub>, and SO<sub>2</sub>. However, as a general matter, the benefits associated with reductions in exposure to fine PM account for more than 90 percent of estimated health benefits. Other studies have obtained similar results for reductions in NO<sub>x</sub> emissions. For example, Muller and Mendelsohn estimated negative damage estimates for NO<sub>x</sub> reductions from sources located in 42 counties in a number of different major metropolitan areas (Muller and Mendelsohn, AER 2009, 1726, Web Appendix B).



of the NAAQS at roadway monitors requiring further control of NO<sub>x</sub> emissions from mobile sources) could substantially alter the estimated benefits relative to the scenario evaluated by EPA.

Another critical area is the development of a quantitative uncertainty analysis for the exposure assessment, including the underlying air quality modeling. The 2002 NRC report stated that "...it is difficult to know how much confidence to place in the predictions" without evaluating the uncertainty in air quality modeling (NRC 2002, 6). As an illustration of the potential importance of this uncertainty, the recent NRC report on the Hidden Cost of Energy provides estimates of the benefits per ton associated with controlling emissions of SO<sub>2</sub>, NO<sub>x</sub>, and fine PM from coal-fired power plants that are substantially smaller than EPA's recent estimates (in some cases an order of magnitude smaller; see Table 4) (NRC 2009b). Although a portion of this difference is attributable to a difference in the threshold assumption for the concentration-response relationship, much of the difference in the estimates arises from differences in the air quality modeling used in the NRC report and by EPA.<sup>32</sup> Such differences could significantly alter estimated benefits.

## Summary

Eight years after the 2002 NRC report, EPA's primary response has been largely limited to the completion of an expert elicitation study of the causal relationship between fine PM exposure and premature mortality. EPA has also responded to some of the NRC report recommendations by changing the presentation of its uncertainty analysis; the primary examples include the agency's decision to move its sensitivity analysis into the main RIA health benefits chapter and to round the estimates to fewer significant digits. But, in all other aspects, EPA's basic approach to presenting the uncertainty in its health benefits estimates remains largely unchanged.

First, the array of information presented in EPA's recent RIAs continues to place on the reader the responsibility of assessing the relative weight and plausibility of alternative assumptions and combining this assessment across sources of uncertainty to provide an overall estimate of uncertainty. Second, to the

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<sup>32</sup> The NRC report reports that its estimates of premature mortality differ from EPA's by a factor of four and directly attributes this difference to differences in air quality modeling. (NRC 2009, 73). Krupnick et al. (2006) examined the effect of adopting alternative source-receptor models and reported that there was a 3.5 fold difference in the mean benefit estimates for the two air quality models evaluated in that study (97).

extent that EPA presents a quantitative treatment of uncertainty in its recent RIAs, the analysis focuses on the concentration-response relationship and largely fails to address the uncertainty associated with other key elements in the benefits analysis, such as the estimated change in emissions and exposure, including air quality modeling. Third, the expert elicitation study applies only to the fine PM–premature mortality relationship, and does not address in a similar way the uncertainty in the concentration-response relationship for the other criteria pollutants—especially ozone—subject to the NAAQS. Finally, the expert elicitation study provides a separate perspective on the fine PM–premature mortality relationship but it falls short of yielding the more comprehensive, quantitative representation of uncertainty in the health benefits estimates envisioned by the NRC report.

Thus, EPA’s recent RIAs provide only a qualitative discussion for many of the sources of uncertainty in the analysis, even though outside panels and studies continue to call for improved quantitative uncertainty analysis.<sup>33</sup> Without a quantitative uncertainty analysis that addresses the important sources of uncertainty, it is difficult to know whether the resulting health benefits estimates reflect expected values or where these estimates fall within their associated probability distributions. To paraphrase the NRC report (2002), no estimate can be considered best until the quantitative analysis includes the major sources of uncertainty in the analysis producing that estimate. And if estimates of health benefits do not reflect expected values, then there should be little reason to have any confidence in claims that benefits exceed the costs, or in claims that costs exceed benefits for a particular regulatory action.

The development of a good quantitative uncertainty analysis is clearly a difficult effort—perhaps more difficult than recognized by the 2002 NRC report. It is made all the more difficult by limited budget and staff resources and by the continuing stream of major rulemakings.<sup>34</sup> In the last two years, for example, EPA has developed RIAs for four final or proposed NAAQS rules—ozone, lead, nitrogen dioxide, and sulfur dioxide. With this heavy workload under tight deadlines and limited resources, the agency will continue to face these practical limits in developing a quantitative uncertainty analysis. As a result, the focus

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<sup>33</sup> NRC 2007a, 116-117; NRC 2007b, 6-8; Krupnick et al. 2006, 224-227; Keohane 2009, 45-47.

<sup>34</sup> In response to the 2006 GAO report, EPA staff indicated that budget and staff to devote to the RIA effort were limited. In addition, they reported that some of the recommendations require a long-term research and development effort. For example, EPA has such research underway to assess the relative toxicity of different components of particulate matter. They also suggested that the cost of doing the work necessary to meet some of the recommendations might outweigh the value of the added information (GAO 2006, 10-11 and 30-36).

should be on examining those areas that are likely to represent the largest sources of uncertainty.

### **A Future Agenda**

The discussion above identifies some further steps that EPA ought to take in developing a quantitative uncertainty analysis. The Harvard-Kuwait study (2008) provides a second expert elicitation study of the fine PM-premature mortality relationship and takes the next step of combining the estimates provided by the experts. EPA ought to incorporate this second study in its discussion of the uncertainty in the concentration-response estimate for fine PM and further explore the merits of combining the estimates of experts. In addition, EPA should conduct a similar expert elicitation for the relationship between ozone and premature mortality.

Several recent studies—the 2009 NRC report on the hidden costs of energy and the Fann et al. (2009) article—suggest the importance of providing a quantitative analysis of the uncertainty associated with air quality modeling for changes in SO<sub>2</sub> and NO<sub>x</sub> emissions on air quality. EPA needs to develop a probabilistic treatment of the air quality modeling linking emissions to exposure. In summary, the same questions with the quality of uncertainty analysis arise repeatedly with the periodic review of the NAAQS required by the CAA—and with the application of these NAAQS RIA effect estimates to RIAs for other rules (for example, mobile source rules). Therefore, it is imperative for EPA take these further steps in developing a better quantitative uncertainty analysis.

**Tables**

**Table 1. Quantitative Uncertainty Analysis for Key Elements in Estimating Health Benefits for Rules Revising Recent NAAQS**

	<b>GAO Assessment, 2006</b>	<b>Final 2006 PM NAAQS RIA</b>	<b>Recent EPA Regulatory Analysis</b>
<b>I. Boundaries and Baselines</b>			
Population demographics and heterogeneity	Not applied.	No further progress.	No further progress.
Health baselines	Not applied.	No further progress.	No further progress.
<b>II. Exposure Assessment</b>			
Estimated changes in emissions	Not applied; R&D under development.	No further progress.	No further progress.
Air quality modeling	Not addressed.	No further progress.	No further progress.
Ambient air measures adequately reflect actual exposure	Partially applied. However, EPA has not yet assessed how human-time activity patterns affect exposure to PM.	No further progress.	Sensitivity analysis on the geographic scope of exposure estimates for lead, NO <sub>2</sub> , and SO <sub>2</sub> RIAs (e.g. exposure within a 30 km radius v. exposure within a 15 km radius).
<b>III. Health Outcomes</b>			
Assumption of causality	Applied. RIA refers readers to prior RIA for information.	Same plus EPA completed expert elicitation study.	No additional progress beyond PM NAAQS RIA.
Validity and precision of C-R function	Applied. EPA is undertaking an expert elicitation study to evaluate C-R function for fine PM.	EPA completed expert elicitation study for C-R function for fine PM.	See Table 2.
Toxicity of PM components	Not applied; R&D underway.	Same	Not applicable for criteria pollutant of concern in rule.

Sources: U.S. EPA 2006, 2008a, 2008 b, 2009a, and 2009b.

Fraas: EPA's Treatment of Uncertainty in Air Rules Analysis: Status

**Table 2. Quantitative Uncertainty Analysis in Developing a Concentration-Response Function for Estimating Health Benefits for Recent NAAQS Rules**

	Ozone NAAQS	Lead NAAQS	NO2 NAAQS	SO2 NAAQS
<b>Primary Analysis</b>				
Mean Based on Effect Estimate	Yes <sup>a</sup>	Yes <sup>b</sup>	Yes <sup>b</sup>	Yes <sup>b</sup>
95% Confidence Interval using std. error of selected studies	Yes <sup>a</sup>	No	Yes <sup>b</sup>	Yes <sup>b</sup>
<b>Sensitivity Analysis/Primary Analysis</b>	None	Yes <sup>c</sup>	Yes	Yes
One factor at a time	n/a	Yes	Yes	Yes
Presentation in Appendix only	n/a	Analysis in the benefits section.	Analysis in the benefits section.	Analysis in the benefits section.
<b>Types of Sensitivity Analysis/Primary Analysis</b>				
Exposure estimate scope	n/a	Yes	Yes	Yes
Threshold	n/a	No	Yes	No
Selection of studies	n/a	Yes	Yes	Yes
Simulated attainment	n/a	No	Yes	No
<b>PM Co-Benefits</b>				
Expert Elicitation Study	Yes	Yes	Yes	Yes
Confidence Intervals	No	No	No	No
Sensitivity Analysis	Only in Appendix.	None	Analysis in the benefits section.	Analysis in the benefits section.
<b>Presentation in Executive Summary</b>	No, only qualitative discussion.	No, only qualitative discussion.	No, only qualitative discussion.	No, only qualitative discussion.

<sup>a</sup> Premature mortality and morbidity

<sup>b</sup> Morbidity only

<sup>c</sup> Included different dose-response functions (slopes). Sensitivity analysis also included the effect of different air-to-blood ratios and non-air background.

Sources: U.S. EPA 2006, 2008a, 2008b, 2009a, and 2009b.

**Table 3. Monetized Reductions in Fine PM Precursor Emissions by Source and Location**

National	\$720,000	\$550,000	\$460,000	\$40,000	\$82,000	\$59,000	\$2,400	\$38,000	\$95,000	\$15,000	\$9,700	\$10,000
Atlanta	\$670,000	\$590,000	\$620,000	\$48,000	\$15,000	\$42,000	\$1,200	-\$4,100	\$56,000	\$7,900	-\$4,500	-\$4,100
Chicago	\$510,000	\$580,000	\$600,000	\$29,000	\$18,000	\$15,000	\$3,100	\$36,000	\$100,000	\$1,100	\$2,000	-\$8,700
Dallas	\$1,100,000	\$790,000	\$1,100,000	\$140,000		\$29,000	\$600	\$16,000	\$36,000	\$34,000	\$920	\$370
	\$280,000	\$450,000	\$220,000	\$75,000	\$6,400	\$19,000	\$1,400	\$10,000	\$58,000	\$3,200	\$3,800	\$2,700
	\$570,000	\$710,000	\$780,000	\$14,000	\$74,000	\$50,000	\$4,300	\$53,000	\$140,000	\$1,500	-\$2,800	-\$8,200
	\$2,500,000	\$1,700,000	\$980,000	\$73,000		\$550,000	\$2,000	\$15,000	\$43,000	\$11,000	-\$2,100	-\$680
	\$140,000	\$150,000	\$65,000	\$15,000		\$9,100	\$2,600	\$29,000	\$43,000		\$4,200	\$1,500
	\$910,000	\$560,000	\$720,000	\$140,000	\$350,000	\$46,000	\$5,700	\$36,000	\$140,000	\$28,000	\$28,000	\$43,000
	\$500,000	\$570,000	\$720,000	\$54,000	\$6,300	\$52,000	\$560	\$18,000	\$49,000	\$120,000	-\$2,300	-\$8,100
	Area source carbon	Mobile source carbon	EGU & Non-EGU carbon	Area source SOx	EGU SOx	Non-EGU SOx	VOC	Area source NH3	Mobile source NH3	EGU NOx	Non-EGU NOx	Mobile source NOx

Source: Fann et al. 2009, 174. Figure 4.

**Table 4. Benefit per Ton Estimates for Emissions of Direct PM and Precursor Pollutants from EGUs**

	2009 NRC Report <sup>a</sup>		NO <sub>2</sub> NAAQS <sup>b</sup>	SO <sub>2</sub> NAAQS <sup>c</sup>
	Mean	50th percentile		
<b>Direct PM<sub>2.5</sub></b>	\$9,500	\$7,100	\$280,000	\$230,000
<b>PM<sub>2.5</sub> Precursor Pollutants</b>				
SO <sub>2</sub>	\$5,800	\$5,800	NA	\$42,000
NO <sub>x</sub>	\$1,600	\$1,300	\$7,600	\$7,600

*Note:* Estimates based on the effect estimate for the concentration-response relationship from the Pope et al. (2002) study.

<sup>a</sup> Benefit per ton estimates for the reduction of direct PM and for precursor emissions from the mean and 50th percentile EGUs over the distribution of 406 coal-fired plants considered in the NRC report (NRC 2009b, 65).

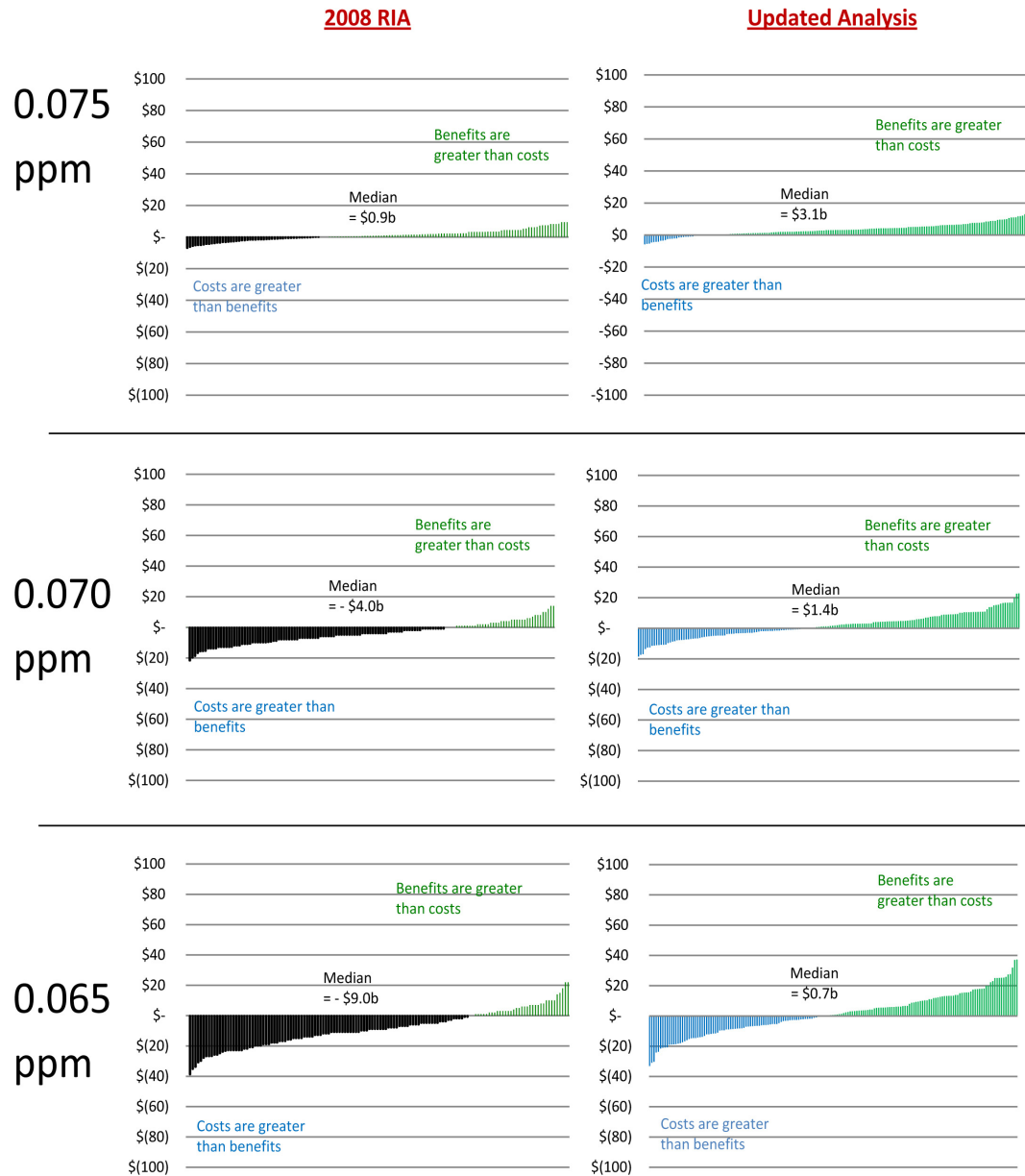
<sup>b</sup> Benefit per ton estimates from the draft RIA for the proposed NO<sub>2</sub> NAAQS rule (U.S. EPA 2009a, Table 5.7, 5-28).

<sup>c</sup> Benefit per ton estimates from the draft RIA for the proposed SO<sub>2</sub> NAAQS rule (U.S. EPA 2009b, Table 5.9, 5-31).

*Note:* These graphs show all combinations of the 6 different ozone mortality functions and assumptions, the 14 different PM mortality functions, and the 2 cost methods. These combinations do not represent a distribution.

Source: EPA 2010.

**Figure 1. Comparison of Net Benefits in Updated Analysis to 2008 Ozone NAAQS RIA\***



*Note:* These graphs show all combinations of the 6 different ozone mortality functions and assumptions, the 14 different PM mortality functions, and the 2 cost methods. These combinations do not represent a distribution.

*Source:* EPA 2010.



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